

Express Mail Label : EL 951611709 US

Date of Mailing: February 25, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

J1046 U.S. PTO  
10/084843  
02/25/02

In re application of:

REED et al.

Application No.: Unassigned

Filed: Herewith

For: COMPOUNDS AND METHODS  
FOR IMMUNOTHERAPY AND  
DIAGNOSIS OF TUBERCULOSIS

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Assistant Commissioner for Patents  
Washington, D.C. 20231

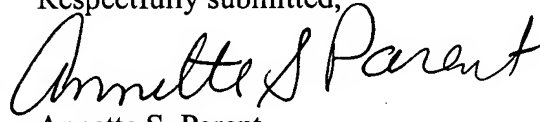
Sir:

The references cited on attached forms PTO-1449 are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/072,967, filed May 5, 1998 (Attorney Docket No. 014058-008590US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

A handwritten signature in black ink that reads "Annette S. Parent". The signature is written in a cursive style with a large, stylized "A" and "P".

Annette S. Parent  
Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP  
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PATENT

I hereby certify that on the date specified below, this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

MAY 22, 1998  
Date

David J. Maki  
David J. Maki

J1046 U.S. PRO  
10/084843  
02/25/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Steven G. Reed et al.  
Application No. : 09/072,967  
Filed : May 5, 1998  
For : COMPOUNDS AND METHODS FOR IMMUNOTHERAPY  
AND DIAGNOSIS OF TUBERCULOSIS

Docket No. : 210121.411C9

Date : May 22, 1998

Assistant Commissioner for Patents  
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449. This application is a continuation-in-part and relies, under 35 U.S.C. § 120, on the earlier filing date of prior U.S. Application No. 09/025,197, filed February 18, 1998; which is a continuation-in-part of U.S. Application No. 08/942,578, filed October 1, 1997; which is a continuation-in-part of U.S. Application No. 08/818,112, filed March 13, 1997; which is a continuation-in-part of U.S. Application No. 08/730,510, filed October 11, 1996; which claims priority from PCT Application No. PCT/US 96/14674, filed August 30, 1996; and is a continuation-in-part of U.S. Application No. 08/680,574, filed July 12, 1996; which is a continuation-in-part of U.S. Application No. 08/659,683, filed June 5, 1996; which is a continuation-in-part of U.S. Application No. 08/620,874, filed March 22, 1996; which is a continuation-in-part of U.S. Application No. 08/533,634, filed September 22, 1995; which is a continuation-in-part of U.S. Application No. 08/523,436, filed on September 1, 1995, now abandoned. The references listed on the attached Form PTO-1449 were submitted to and/or cited by the Office in this prior application and, therefore, are not required to be provided in the present application. However, the following references were not submitted to and/or cited by the Office and are being submitted herewith:

- US 5,108,745
- WO 95/14713

- Lowrie et al., "Towards a DNA vaccine against tuberculosis,"  
*Vaccine* 12(16):1537-1540, 1994.

As to any reference previously submitted, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully submitted,

Steven G. Reed et al.

SEED and BERRY LLP



---

David J. Maki

Registration No. 31,392

DJM:jto

Enclosures:

Postcard

Form PTO-1449

Cited References (3)

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PATENT

I hereby certify that on the date specified below, this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

JUNE 3, 1998  
Date

David J. Maki  
David J. Maki



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Steven G. Reed et al.  
Application No. : 09/072,967  
Filed : May 5, 1998  
For : COMPOUNDS AND METHODS FOR IMMUNOTHERAPY  
AND DIAGNOSIS OF TUBERCULOSIS  
Docket No. : 210121.411C9  
Date : June 3, 1998

Assistant Commissioner for Patents  
Washington, DC 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

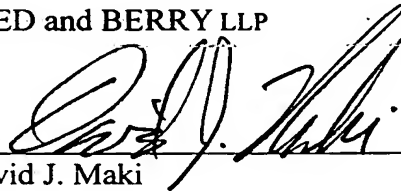
In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449 (copies of the cited references, as required under 37 C.F.R. § 1.98, are enclosed). As to any reference supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Reference AJ (FR 2 244 539) on page 1 of the attached Form PTO-1449, is written in French. Applicants note that United States Patent 3,943,119 (Reference AA on page 1) is a related application that claims identical priority as FR 2 244 539 and is written in English.

Reference AK (FR 2 265 402) on page 1 of the attached Form PTO-1449, is written in French. Applicants note that United States Patent 3,943,119 (Reference AA on page 1) is a related application that claims identical priority as FR 2 265 402 and is written in English.

Please acknowledge receipt of this Supplemental Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully submitted,  
Steven G. Reed et al.  
SEED and BERRY LLP



David J. Maki  
Registration No. 31,392

DJM:jto

Enclosures:

Postcard  
Form PTO-1449  
Cited References (8)

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(206) 622-4900  
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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
210121.411C9APPLICATION NO.  
09/072,967**INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

APPLICANTS  
Steven G. Reed et al.FILING DATE  
May 5, 1998

GROUP ART UNIT

J1046 U.S. PTO  
10/08/94**U.S. PATENT DOCUMENTS**

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE    | NAME    | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|---------|---------|-------|----------|-------------------------------|
|                      | AA | 5,108,745       | 4/28/92 | Horwitz | 424   | 92       |                               |
|                      | AB |                 |         |         |       |          |                               |
|                      | AC |                 |         |         |       |          |                               |
|                      | AD |                 |         |         |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER | DATE     | COUNTRY                      | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|----------|------------------------------|-------|----------|-------------|----|
|  |    |                 |          |                              |       |          | YES         | NO |
|  | AE | EP 419 355 A1   | 3/27/91  | EPO                          |       |          |             |    |
|  | AF | EP 519 218 A2   | 12/23/92 | EPO (WPI Acc. No. 92-390976) |       |          |             | X  |
|  | AG | WO 88/05823     | 8/11/88  | PCT                          |       |          |             |    |
|  | AH | WO 91/04272     | 4/4/91   | PCT                          |       |          |             |    |
|  | AI | WO 91/14448     | 10/3/91  | PCT                          |       |          |             |    |

**OTHER PRIOR ART** (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |   |
|--|----|---|
|  | AJ | Andersen and Hansen, "Structure and Mapping of Antigenic Domains of Protein Antigen b, a 38,000-Molecular-Weight Protein of <i>Mycobacterium tuberculosis</i> ," <i>Infection and Immunity</i> 37(8):2481-2488, 1989. |
|  | AK | Andersen et al., "Identification of Immunodominant Antigens during Infection with <i>Mycobacterium tuberculosis</i> ," <i>Scand. J. Immunol.</i> 36:823-831, 1992.  |
|  | AL | Andersen, P., "Effective Vaccination of Mice against <i>Mycobacterium tuberculosis</i> Infection with a Soluble Mixture of Secreted Mycobacterial Proteins," <i>Infection and Immunity</i> 62(6):2536-2544, 1994.     |
|  | AM | Ausebel et al., "Isolation of Proteins for Microsequence Analysis," in <i>Current Protocols in Molecular Biology</i> , Wiley & Sons, New York, 1993, pgs. 10.19.1-10.19.12.   |
|  | AN | Barnes et al., "Immunoreactivity of a 10-kDa Antigen of <i>Mycobacterium tuberculosis</i> ," <i>The Journal of Immunology</i> 148(6):1835-1840, 1992.   |
|  | AO | Boesen et al., "Human T-Cell Responses to Secreted Antigen Fractions of <i>Mycobacterium tuberculosis</i> ," <i>Infection and Immunity</i> 63(4):1491-1497, 1995.   |
|  | AP | Borremans et al., "Cloning, Sequencing Determination, and Expression of a 32-Kilodalton-Protein Gene of <i>Mycobacterium tuberculosis</i> ," <i>Infection and Immunity</i> 57(10):3123-3130, 1989.                    |

EXAMINER

DATE CONSIDERED

|   |    |   |          |                                     |       |                               |                               |
|---|----|---|----------|-------------------------------------|-------|-------------------------------|-------------------------------|
| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |          | ATTY. DOCKET NO.<br>210121.411C9    |       | APPLICATION NO.<br>09/072,967 |                               |
| <b>INFORMATION DISCLOSURE STATEMENT</b><br><i>(Use several sheets if necessary)</i>   |    |   |          | APPLICANTS<br>Steven G. Reed et al. |       |                               |                               |
|   |    |   |          | FILING DATE<br>May 5, 1998          |       | GROUP ART UNIT                |                               |
| <b>U.S. PATENT DOCUMENTS</b>  |    |   |          |                                     |       |                               |                               |
| *EXAMINER<br>INITIAL  |    | DOCUMENT NUMBER   | DATE     | NAME                                | CLASS | SUBCLASS                      | FILING DATE<br>IF APPROPRIATE |
|   | AA |   |          |                                     |       |                               |                               |
|   | AB |   |          |                                     |       |                               |                               |
|   | AC |   |          |                                     |       |                               |                               |
|   |    |   |          |                                     |       |                               |                               |
|   | AD |   |          |                                     |       |                               |                               |
| <b>FOREIGN PATENT DOCUMENTS</b>   |    |   |          |                                     |       |                               |                               |
|   |    | DOCUMENT NUMBER   | DATE     | COUNTRY                             | CLASS | SUBCLASS                      | TRANSLATION                   |
|   |    |   |          |                                     |       |                               | YES    NO                     |
|   | AE | WO 92/04049   | 3/19/92  | PCT                                 |       |                               |                               |
|   | AF | WO 92/14823   | 9/3/92   | PCT                                 |       |                               |                               |
|   | AG | WO 92/21758   | 12/10/92 | PCT                                 |       |                               |                               |
|   | AH | WO 94/00493   | 1/6/94   | PCT                                 |       |                               |                               |
|   | AI | WO 95/01440   | 1/12/95  | PCT                                 |       |                               |                               |
|   | AJ | WO 95/01441   | 1/12/95  | PCT                                 |       |                               |                               |
| <b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>  |    |   |          |                                     |       |                               |                               |
|   | AK | Content et al., "The Genes Coding for the Antigen 85 Complexes of <i>Mycobacterium tuberculosis</i> and <i>Mycobacterium bovis</i> BCG Are Members of a Gene Family: Cloning, Sequence Determination, and Genomic Organization of the Gene Coding for Antigen 85-C of <i>M. tuberculosis</i> ," <i>Infection and Immunity</i> 59:3205-3212, 1991. |          |                                     |       |                               |                               |
|   | AL | Horowitz et al., "Protective immunity against tuberculosis induced by vaccination with major extracellular proteins of <i>Mycobacterium tuberculosis</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 92:1530-1534, 1995.   |          |                                     |       |                               |                               |
|   | AM | Lowrie et al., "Towards a DNA vaccine against tuberculosis," <i>Vaccine</i> 12(16):1537-1540, 1994.   |          |                                     |       |                               |                               |
|   | AN | Matsumoto et al., "Cloning and Sequencing of a Unique Antigen MPT70 from <i>Mycobacterium tuberculosis</i> H37Rv and Expression in BCG Using <i>E. coli</i> -Mycobacteria Shuttle Vector," <i>Scand. J. Immunol.</i> 41:281-287, 1995.  |          |                                     |       |                               |                               |
|   | AO | Nagai et al., "Isolation and Partial Characterization of Major Protein Antigens in the Culture Fluid of <i>Mycobacterium tuberculosis</i> ," <i>Infection and Immunity</i> 59(1):372-382, 1991.   |          |                                     |       |                               |                               |
|   | AP | Oettinger and Andersen, "Cloning and B-Cell-Epitope Mapping of MPT64 from <i>Mycobacterium tuberculosis</i> H37Rv," <i>Infection and Immunity</i> 62(5):2058-2064, 1994.  |          |                                     |       |                               |                               |
| EXAMINER  |    |   |          | DATE CONSIDERED                     |       |                               |                               |
| <p>* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant(s).</p> |    |   |          |                                     |       |                               |                               |



|  |  |                                     |                               |
|--|--|-------------------------------------|-------------------------------|
| FORM PTO-1449<br>(REV. 7-80)   | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.<br>210121.411C9    | APPLICATION NO.<br>09/072,967 |
| <b>INFORMATION DISCLOSURE STATEMENT</b><br>(Use several sheets if necessary) |  | APPLICANTS<br>Steven G. Reed et al. |                               |
|  |  | FILING DATE<br>May 5, 1998          | GROUP ART UNIT                |

### U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|------|------|-------|----------|-------------------------------|
|                      | AA |                 |      |      |       |          |                               |
|                      | AB |                 |      |      |       |          |                               |
|                      | AC |                 |      |      |       |          |                               |
|                      |    |                 |      |      |       |          |                               |
|                      | AD |                 |      |      |       |          |                               |

### FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE   | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|--------|---------|-------|----------|-------------|----|
|  |    |                 |        |         |       |          | YES         | NO |
|  | AE | WO 95/14713     | 6/1/95 | PCT     |       |          |             |    |
|  | AF |                 |        |         |       |          |             |    |
|  | AG |                 |        |         |       |          |             |    |
|  | AH |                 |        |         |       |          |             |    |

### OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |  |
|--|----|--|
|  | AI | Pal and Horwitz, "Immunization with Extracellular Proteins of <i>Mycobacterium tuberculosis</i> Induces Cell-Mediated Immune Responses and Substantial Protective Immunity in a Guinea Pig Model of Pulmonary Tuberculosis," <i>Infection and Immunity</i> 60(11):4781-4792, 1992. |
|  | AJ | Romain et al., "Isolation of a proline-rich mycobacterial protein eliciting delayed-type hypersensitivity reactions only in guinea pigs immunized with living mycobacteria," <i>Proc. Natl. Acad. Sci. USA</i> 90:5322-5326, 1993.   |
|  | AK | Romain et al., "Preparation of Tuberculin Antigen L," <i>Ann. Inst. Pasteur/Microbiol.</i> 136B:235-248, 1985.   |
|  | AL | Wallis et al., "Identification of Antigens of <i>Mycobacterium tuberculosis</i> Using Human Monoclonal Antibodies," <i>J. Clin. Invest.</i> 84:214-219, 1989.  |
|  | AM | Wiker and Harboe, "The Antigen 85 Complex: a Major Secretion Product of <i>Mycobacterium tuberculosis</i> ," <i>Microbiological Reviews</i> 56(4):648-661, 1992.   |
|  | AN | Yamaguchi et al., "Cloning and Characterization of the Gene for Immunogenic Protein MPB64 of <i>Mycobacterium bovis</i> BCG," <i>Infection and Immunity</i> 57(1):283-288, 1989.   |
|  | AO | Young et al., "Screening of a Recombinant Mycobacterial DNA Library with Polyclonal Antiserum and Molecular Weight Analysis of Expressed Antigens," <i>Infection and Immunity</i> 55(6):1421-1425, 1987.   |

|          |                 |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

\* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
210121.411C9APPLICATION NO.  
09/072,967**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

APPLICANTS  
Steven G. Reed et al.FILING DATE  
May 5, 1998

GROUP ART UNIT

J1046 U.S. PTO  
10/084843**U.S. PATENT DOCUMENTS**

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE   | NAME           | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|--------|----------------|-------|----------|-------------------------------|
|                      | AA | 3,943,119       | 3/9/76 | Tsumita et al. | 260   | 112.5R   |                               |
|                      | AB |                 |        |                |       |          |                               |
|                      | AC |                 |        |                |       |          |                               |
|                      | AD |                 |        |                |       |          |                               |
|                      | AE |                 |        |                |       |          |                               |
|                      | AF |                 |        |                |       |          |                               |
|                      | AG |                 |        |                |       |          |                               |
|                      | AH |                 |        |                |       |          |                               |
|                      | AI |                 |        |                |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER | DATE     | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|----------|---------|-------|----------|-------------|----|
|  |    |                 |          |         |       |          | YES         | NO |
|  | AJ | FR 2 244 539    | 5/23/75  | French  |       |          |             |    |
|  | AK | FR 2 265 402    | 11/28/75 | French  |       |          |             |    |
|  | AL | WO 95/31216     | 11/23/95 | PCT     |       |          |             |    |
|  | AM | WO 96/15241     | 5/23/96  | PCT     |       |          |             |    |
|  | AN | WO 96/23885     | 8/8/96   | PCT     |       |          |             |    |
|  | AO | WO 97/09428     | 3/13/97  | PCT     |       |          |             |    |
|  | AP | WO 97/09429     | 3/13/97  | PCT     |       |          |             |    |

**OTHER PRIOR ART** (Including Author, Title, Date, Pertinent Pages, Etc.)

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|--|----|--|--|
|  | AR |  |  |
|  | AS |  |  |
|  | AT |  |  |

EXAMINER

DATE CONSIDERED

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